expensive and time consuming. The present invention provides an improved way of maintaining patient information in confidence when such materials are disposed of.

The present invention contemplates a number of embodiments which disassociate the patient identity from the patient's medical information. In one embodiment, shown in Fig. 3 of the drawings in the present application, a data carrier 10 includes a health information label 14, and a masking label 28. The data carrier is configured to permit the association between the name of the patient ("John Doe" in the example) and the health related information ("Amoxicillin 250 mg" in the example) to be obscured when the data carrier is about to be discarded. The data carrier includes a release liner 12. The health information label 14 has an upper surface 16 and a lower surface, and a pressure sensitive adhesive coating on the lower surface of the health information label 14 which secures the health information label to the release liner 12. The health information label 14 is made up of a first portion 18 and a second portion 20, with the first and second portions being separated by a line of die cut perforations 22. Alternatively, die cut line 22 may be a continuous die cut. The label 14 includes a first area 24 on the upper surface 16 for indicia specifying health related information, such as an identification of medication, and a second area 26 on the upper surface 16 for indicia specifying the identity of a patient.

Beneath the masking label 28 is a die cut 34 in the release liner defining a removable liner piece 36. The removable liner piece 36 is removed from the release liner with the health information label 14 and remains with it when the health information label 14 is applied to a surface, such as for example the outer surface of a pharmaceutical container. When used in this manner, the liner piece 36 remains between the label 14 and the container surface and is surrounded along three edges by adhesive that secures the lower surface of the label 14 to the container surface. When the container is emptied and about to be discarded, the masking label 28 is removed from the liner piece 36 so that the masking label 28 can be applied over one or both of the first and second areas 24 and 26 to obscure the association between the name of the patient and the health related information.

The pressure sensitive adhesive coating on the lower surface of the label 14 comprises a permanent adhesive. As a consequence, applying the masking label 28 over one or both of the first and second areas 24 and 26 obscures the association between the name of the patient and the health related information, and an attempt to remove the masking label 28 from the health information label 14 will result in the destruction of the label 14 to a degree needed to render the covered information illegible.

Claims 1, 2, 4, 13 and 15 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Blank (US 7,048,308). The Blank reference is relied upon in rejecting these claims conjunction with the citation of *In re Gulack*, 217 USPQ 401 (Fed.Cir. 1983).

The Examiner discusses the Blank reference but never explains the deficiencies in the disclosure of Blank, never explains what modifications are to be made to the disclosure of Blank to meet these deficiencies, and never explains what would motivate a person or ordinary skill to make those modifications. A properly articulated rejection under 35 U.S.C. §103(a) should address all of these points. In this regard, reference is made to MPEP Section 706.02(j), which makes this clear. The following is taken from MPEP Section 706.02(j).

706.02(j) Contents of a 35 U.S.C. 103 Rejection

35 U.S.C. 103 authorizes a rejection where, to meet the claim, it is necessary to modify a single reference or to combine it with one or more other references. After indicating that the rejection is under 35 U.S.C. 103, the examiner should set forth in the Office action:

(A) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate,

(B) the difference or differences in the claim over the applied reference(s),

(C) the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter, and

(D) an explanation why one of ordinary skill in the art at the time the invention was made would have been motivated to make the proposed modification.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

It actually appears that the Examiner may be asserting that the claims 1, 2, 4, 13, and 15 are anticipated by Blank, rather than that the claims are obvious in view of Blank. In the Office Action, the Examiner never suggests a modification of the Blank disclosure. Naturally, ignoring the need to modify the teachings of Blank frees the Examiner from the task of explaining why such a modification would be obvious to a person of ordinary skill. In making this rejection, the Examiner simply chooses to ignore the claim limitations that relate to indicia which specify the identity of a patient and the patient's health related information. The Examiner denies that he ignores the claim limitations which specify the nature of the printed indicia and the location of the printed indicia, asserting instead that he concluded "that the printed matter would not be deemed as having patentable weight." It is submitted that this is a distinction without a difference. In either event, the Examiner fails to address the differences between the claim and the Blank reference that involve the content of the printed matter or position of the printed matter on the data carrier.

The Blank reference discloses a label construction that differs significantly from the present invention. As shown in FIG. 3 of Blank, the main label 14, including central tab 32, is initially removed from the liner 18 to expose the adhesive 20 on the back side of the label rim. Note that no adhesive is exposed on the back side of the tab 32 by virtue of a liner tab 40. The label is adhered to a pharmaceutical container 26 using the exposed adhesive 20 around the label rim. The face side of the main label 14 and its central tab 32 expose to view all of the patient identification and patient health related information, information which it is desired to keep confidential.

In Blank, when container 26 is emptied, before it is discarded, the confidential information 30 is removed from the container by tearing away the printed tab 32 from the label rim 34. The rim 34 remains permanently bonded to the container. The slits 36 in the main label provide a convenient means for initiating tearing of the label tab 32 from the remaining label rim. The liner 18 includes a diecut 38, spaced inboard from the perimeter of the liner to define a central liner tab 40. The liner tab 40 is laminated to, and corresponds substantially in size and configuration with, the label tab 32. In the arrangement of Fig. 3, the printed tab 32 could not be used as a masking label since its adhesive layer is covered by the liner tab 40, and also since the patient information that should be masked is in fact carried on the printed tab 32. Fig. 5 of Blank shows a similar arrangement in which the liner tab 40 carries a release coating 44 which permits, the label tab 32 to be separated from the liner tab 40 after the tab 32 and the tab 40 have been removed from the main label so that the tab 32 can then be bonded to another object, such as a record sheet. In this arrangement, as in the arrangement of Fig. 3 of Blank, the tab 32 carries both the patient name and the patient medication. As a result, there is no disassociation of the patient identity information from the patient medical information in the Blank data carrier.

The pending claims clearly distinguish the present invention from Blank. Claim 1 specifies that a data carrier for providing health related information regarding a patient

includes a health information label that has a first area for indicia specifying health related information and a second area for indicia specifying the identity of the patient. The carrier further includes a masking label that is integral with the health information label. A die cut in the release liner defines a removable liner piece beneath the masking label. The liner piece remains on the back of the health information label when the health information label is applied to a surface, "said removable liner piece permitting the removal of said masking label from said health information label so that said masking label can be applied over one or both of said first and second areas to obscure the association between the identity of the patient and said health related information when the data carrier is to be discarded." Blank differs significantly from this in several respects. Blank does not have a masking label that is integral with a health information label with the health information label having a first area for indicia specifying health related information and a second area for indicia specifying the identity of the patient, as called for in claim 1. Also, Blank does not have first and second portions of a health information label with first and second areas on the first portion and a masking label on a second portion, and a line of die cut perforations extending between the portions, as called for in claim 2.

Similarly, independent claim 13 is distinguishable from the Blank reference on a number of bases. Blank in no way suggests a "second label configured such that upon removing said first label from the release liner, said second label remains with said first label when the first label is adhesively applied to a surface, and when said second label is subsequently separated from said first label, said second label is adapted to disassociate the identity of said patent from said health related information." As is apparent from Fig. 3 of Blank, when the label tab 32 is removed from the balance of the label, both the patient identity and the medical information remain associated.

The Examiner relies on *In re Gulack* as a justification for giving no patentable weight to claim limitations that recite the type of information that is printed in printed in first and second areas of the health information label, and claim limitations that specify where those areas are located in relation to the balance of the claimed structural elements. In this regard, the Examiner distorts the holding of *In re Gulack*, and ignores

its facts. *In re Gulack* did not broadly hold that printed matter claim limitations are not to be given patentable weight in assessing the patentability of the claim. In point of fact, it held just the opposite. The invention of *In re Gulack* was held to be patentable over the prior art precisely because the claims included limitations to printed matter that were not ignored and that distinguished those claims from the prior art.

In re Gulack dealt with a "band," such as an endless loop of paper, on which were printed a plurality of digits at regularly spaced intervals. The digits were integers that were generated by a specific algorithm. This band was capable of being used for "magic tricks" and also "to display various aspects of number theory." In the *Gulack* case, the Board had affirmed a rejection based on a prior art band that carried different indicia. The Board had given no patentable weight to the claim limitations regarding the printed digits. The Federal Circuit reversed the Board, holding that the claim limitations as to the printed numbers could not be ignored in comparing the claim to the prior art. The Court held that the printed matter is to be considered to establish patentability if the printed matter is functionally related to the substrate on which it is printed.

In the *Gulack* case, the Court found this functional relationship in that (1) the band "supports" the digits, and (2) there is an endless sequence of such digits with each digit in a unique position with respect to every other digit in the endless loop. This is similar to the claimed invention in the present application. The health information label supports the indicia specifying the health related information and the identity of the patient in the first and second areas, with the position and size of the first and second areas being such that the masking label can be applied over one or both of these areas to obscure the association between the identity of the patient and the health related information.

In re Ngai, 70 USPQ2d 1862 (Fed.Cir. 2004) is a Federal Circuit case, also dealing with the issue of printed matter, which interprets and explains *In re Gulack*. The Federal Circuit in *In re Ngai* held that the claim limitation of an instruction sheet packed with a prior art RNA testing kit was not a limitation that rendered the claim to the kit

patentable, even though the method of use specified to be printed on the sheet was non-obvious. *In re Gulack* was distinguished by the Federal Circuit. The applicant, according to the *Ngai* Court, was entitled only to method claims on the new method of using the kit, not apparatus or article claims on the kit *per se*. The printed matter in *In re Ngai* was printed on a separate sheet of paper. In point of fact, the printed matter simply conveyed information and it was unimportant where the printed indicia were printed - the location of the printed matter simply didn't matter because there was no functional relationship between the printed matter and the balance of the elements (the kit components) that were listed in the claim.

The present invention is completely different than that of *In re Ngai* (unpatentable) and very similar to that of *In re Gulack* (patentable) in so far as the relationship between the printed matter and the balance of the claim elements goes. In *In re Gulack*, it was important that the numbers appeared on the endless band, and it was important where the numbers appeared on the endless band. This is because there was a functional relationship between the printed matter and the band. If the numbers were not in the correct position on the endless band, the *Gulack* device would not work. In *In re Ngai*, it really did not matter where the instructions were printed - on a sheet of paper, on a container, etc. - because the printed instructions did not have functional relationship with the kit components and the kit could be used according to the instructions regardless where those instructions were printed.

The invention in the present application contemplates printed matter that is functionally related to the structure of the invention. The masking label is sized so that it can be applied over one or both of the first and second areas to obscure the association between the identity of the patient and the health related information. In the present invention, it matters where the first and second areas are located, and it matters that at least one of the first and second areas is not on the masking label so that the masking label can be applied over one or both of the first and second areas to obscure the association between the name of the patient and the health information. The Blank reference is distinguishable on just this basis. Both the name of the patient and the

health information are printed on a central label tab 32, and this precludes the disassociation that is the object of the present invention.

Claim 6 has been rejected under 35 U.S.C. §103(a) as unpatentable over Blank in view of Stone et al (US 4,549,750). Claim 6 depends from claim 1 and is patentable over the Blank reference for the same reasons presented above with respect to claim 1. Stone does nothing to cure the defects of the rejection based on the Blank reference. Neither Blank nor Stone teaches a masking label as called for in the claim. Further, the combination of these references is clearly a matter of impermissible hindsight.

It is submitted that all of the claims currently presented in the instant application are in condition for allowance. Early notification of favorable action is respectfully requested.

Respectfully submitted,

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